IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Norio INOMATA et al.

Examiner: Michael L. Borin, Ph.D.

Application No.: 09/171,928

Group Art Unit: 1631

Filed: October 5, 1998

Confirmation No.: 8658

Title: PHARMACEUTICAL COMPOSITION FOR TREATMENT OF HEART DISEASE BASED ON CARDIAC HYPERTROPHY

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

The Reply responds to the outstanding Office Action mailed December 5, 2005. Attached hereto is a Petition for a 5-month extension of time, extending the period of response to June 5, 2006.

1. Status of the Claims

Claims 8-11, 21, and 30-35 stand pending as noted in the Office Action Summary. The claims stand subject to a restriction requirement as set out in the Office Action mailed December 5, 2005.

2. Response to Restriction

The Office contends that claims 8-11, 21, and 30-35 are not so linked so as to form a single inventive concept under PCT Rule 13.1. The Office has grouped the claims as follows:

> **Group I:** Claims 8-11, 21, "drawn to method for treatment cardiac disfunction by decreasing pulmonary congestion."
>
> **Group II:** Claims 30-32, "drawn to method for treatment cardiac disfunction by recessing cardiac hypertrophy."
>
> **Group III:** Claims 33-35, "drawn to method of decreasing heart weight."

See Office Action, page 2. The Office further states that each of the Groups "claim a distinct and separate method of treatment: Group I – by decreasing pulmonary congestion, and Groups II and III – by recessing cardiac hypertrophy." Office Action, page 3. The Office

concludes that there is no special technical feature. The Office admits that Groups II and III both act "by recessing cardiac hypertrophy." However, lack of unity is asserted by the Office in view of Blaine et al. (U.S.P.N. 4,652,549, hereinafter "Blaine"). The Office has characterized that the "prominent difference between the methods [of Groups II and III] is that while method of Group II specifies that the effect occurs without causing diuretic and hypotensive effect, method of Group III is inclusive of such a mechanism." Office Action, page 3. The Office then points out that "this distinction was recognized as critical in the course of prosecution of this case". The Office also asserts that there is no unity because the prior art of Blaine allegedly suggests teaching treatment of cardiac hypertrophy using natriuretic peptide receptor activators. The Office alleges that Blaine teaches use of ANP to treat cardiac hypertrophy.

Applicants elect **with traverse** the claims corresponding to **Group III** (*i.e.*, claims 33-35).

Under 37 C.F.R. § 1.499, the examiner *may* require a restriction of the claims. However, it is not a requirement that the claims be restricted into separate groups in any application. There is no burden on the Office to perform the search, because the claims previously were searched. Without burden, Applicants assert that the claims should be rejoined and the restriction withdrawn. It would be burdensome on the Office and on the public respectively to separate the claims in to several applications; the Office would be required to separately search and examine at least 2 additional applications (the subject matter of which has already been searched), and the public would have to identify and assess the three separate patents.

For these reasons, the restriction respectfully should be reconsidered and withdrawn.

As set forth above, the Office has made a statement that the distinction of not causing a diuretic and hypotensive effect under Group II and having those effects with Group III was "critical". For clarity of the record, the term mischaracterizes prior statements. Returning to the prior Office Action and its reference to the July 25, 2002 response by Applicants, Applicants distinguished the difference between cell hypertrophy, caused by increased protein production, and control of water transfer by diuretic effects. On page 15 of the July 25, 2002 response, Applicants stated that "...the administration of ANP either before or after

the onset of cardiac hypertrophy can reduce cardiac hypertrophy and cause involution has great clinical significance."

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above or in the attached papers, such an extension is requested and the fee should also be charged to our Deposit Account.

If any matters remain outstanding, the Examiner is invited to contact the undersigned representative regarding this matter.

Respectfully submitted,
DRINKER, BIDDLE & REATH LLP

Date: June 5, 2006

By: _____

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